REMARKS

Claims 20-23 and 44-79 were examined in the Office Action under reply and rejected under (1) 35 U.S.C. §112, second paragraph, as indefinite; (2) 35 U.S.C §112, first paragraph as nonenabled; and (3) 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. These rejections are traversed for reasons discussed in detail below.

Overview of the Above Amendments

Claims 20 and 56 have been amended in order to recite the subject invention with greater particularity. The term "specific" has been eliminated from the claims and the phrase "directed against" inserted in its place. Support for this amendment can be found throughout the specification at, e.g., page 15, line 3.

Claims 44-55 have been canceled. Cancellation of these claims is without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants reserve the right to bring the canceled claims again in a related application.

Rejection under 35 U.S.C. §112, Second Paragraph

The Office maintained the rejection of claims 20-23 and 44-79 under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Office argues:

> It is not clear what the specificity of this antibody is and it is not clear in this recitation. Does this antibody react only with ≤ 10% N-linked sialic acid but not with more than 10% sialic acid? Does the antibody react with only asialoglycoproteins and not with naked proteins? Thus not knowing the specificity, the claim is not clear.

Office Action, pages 2-3, bridging paragraph.

Applicants continue to traverse the rejection for reasons of record. In particular, the claims previously recited "an isolated antibody specific for said HCV glycoprotein." (Emphasis added). The HCV glycoprotein referred to is defined in the claims as an HCV glycoprotein "having mannose-terminated glycolsylation, wherein less than about 10% of the total N-linked carbohydrate on said HCV glycoprotein is sialic acid." Thus, the claims are clear

that the antibody is specific for an HCV glycoprotein with $\leq$ 10% N-linked sialic acid . Moreover, it is uniformly recognized by those working in the field of immunology that the term "specific" in the context of an antibody does not necessarily denote absolute specificity. Rather, the term is well understood to mean that an antibody molecule is more reactive with (i.e., has greater affinity for) the particular antigen of interest, in this case, the above HCV glycoprotein, than other types of glycoproteins. The use of the term is thus definite.

Notwithstanding the above, applicants have amended the claims to recite that the antibody is "directed against" the recited HCV glycoprotein. Accordingly, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Rejections Under 35 U.S.C. §112, First Paragraph

The Office maintained the rejection of claims 20-23 and 44-79 under 35 U.S.C. §112, first paragraph, as nonenabled. The Office recognizes that the specification is "enabling for concept of using an antigen to make an antibody." However, the Office states the specification "does not reasonably provide enablement for making an antibody 'specific for' the stated antigen." Office Action, page 3. Applicants disagree that antibodies specific for the recited HCV asialoglycoproteins are nonenabled. However, solely for the purpose of advancing prosecution, applicants have amended the claims to recite that the antibody is "directed against" the recited glycoprotein. Accordingly, this basis for rejection has also been overcome.

Claims 20-23 and 44-79 were also rejected under 35 U.S.C. §112, first paragraph, the Office asserting that the specification fails to provide an adequate written description of the invention. The Office alleges "the specification contains no reference to physical properties or structure of the antibody nor does it teach antibodies specifically binding to E1 or E2." Office Action, page 4. Applicants continue to traverse this rejection.

To reiterate, in order to comply with the written description requirement, an applicant's specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, i.e., whatever is now claimed. *Vas Cath Inc. v. Mahurkar,* 19 USPQ 1111, 1117 (Fed. Cir. 1991). The Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim,* 191 USPQ 90 (CCPA 1976). The Office has failed to carry this burden despite applicants' previous request that the Office explain why one of skill in the art would not

recognize that antibodies specific for the recited HCV glycoprotein were contemplated in the present application.

A review of the application as a whole, coupled with the knowledge in the art at the time of filing, evidences that the application contemplates antibodies directed against the recited HCV glycoproteins. The Examiner's attention is directed to the following passage found at page 15, lines 2-4:

> Immunogenic compositions may be administered to animals to induce production of antibodies, either to provide a source of antibodies or to induce protective immunity in the animal.

Moreover, claim 20 as filed recites an assay kit comprising "an antibody specific for said HCV asialoglycoprotein." Thus, based on the disclosure in the specification, coupled with the recitations in claim 20, it is clear that applicants contemplated antibodies as claimed.

Additionally, applicants are not required to explain the well-known structure of an antibody, as implied by the Office. Any basic textbook on immunology published prior to the filing date of the application explains such structure. To reiterate, it is axiomatic that a patent specification "need not teach, and preferably omits, what is well known in the art." See, *Spectra-Physics, Inc. v. Coherent, Inc.*, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986).

In view of the above arguments, then, applicants submit that the claims indeed comply with the written description requirement of 35 U.S.C. §112, first paragraph. Thus, withdrawal of this basis for rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. §112. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 20 and 56 have been amended as follows:

20. (Twice amended) An assay kit for detecting the presence of a hepatitis C virus (HCV) glycoprotein having mannose-terminated glycosylation, wherein less than about 10% of the total N-linked carbohydrate on said HCV glycoprotein is sialic acid, wherein said HCV glycoprotein is selected from the group consisting of a glycoprotein expressed from the E1 region of HCV, a glycoprotein expressed from the E2 region of HCV, and aggregates thereof, said kit comprising:

a solid support;

a mannose-binding protein; and an isolated antibody [specific for] directed against said HCV glycoprotein;

wherein one of said antibody and said mannose binding protein is bound to said solid support.

56. (Amended) An isolated antibody [specific for] directed against a hepatitis C virus (HCV) glycoprotein having mannose-terminated glycosylation, wherein less than about 10% of the total N-linked carbohydrate on said HCV glycoprotein is sialic acid, wherein said HCV glycoprotein is selected from the group consisting of a glycoprotein expressed from the E1 region of HCV, a glycoprotein expressed from the E2 region of HCV, and aggregates thereof, and further wherein said HCV glycoprotein is produced by the method comprising the steps of:

growing a host cell transformed with a structural gene encoding an HCV glycoprotein expressed from the E1 region of HCV or the E2 region of HCV in a suitable culture medium;

causing expression of said structural gene, under conditions inhibiting sialylation; and

isolating said HCV glycoprotein from said cell culture by contacting said HCV glycoprotein with a mannose-binding protein specific for mannose-terminated glycoproteins, and isolating the protein that binds to said mannose-binding protein.

Claims 44-55 have been canceled.

CURRENTLY PENDING CLAIMS

20. (Twice amended) An assay kit for detecting the presence of a hepatitis C virus (HCV) glycoprotein having mannose-terminated glycosylation, wherein less than about 10% of the total N-linked carbohydrate on said HCV glycoprotein is sialic acid, wherein said HCV glycoprotein is selected from the group consisting of a glycoprotein expressed from the E1 region of HCV, a glycoprotein expressed from the E2 region of HCV, and aggregates thereof, said kit comprising:

a solid support;

a mannose-binding protein; and an isolated antibody [specific for] directed against said HCV glycoprotein;

wherein one of said antibody and said mannose binding protein is bound to said solid support.

21. The assay kit of claim 20, wherein said mannose-binding protein is GNA.

22. The assay kit of claim 20, wherein said antibody is bound to said support and said mannose-binding protein is bound to a detectable label.

23. The assay kit of claim 20, wherein said mannose-binding protein is bound to said support and said antibody is bound to a detectable label.

56. (Amended) An isolated antibody [specific for] directed against a hepatitis C virus (HCV) glycoprotein having mannose-terminated glycosylation, wherein less than about 10% of the total N-linked carbohydrate on said HCV glycoprotein is sialic acid, wherein said HCV glycoprotein is selected from the group consisting of a glycoprotein expressed from the E1 region of HCV, a glycoprotein expressed from the E2 region of HCV, and aggregates thereof, and further wherein said HCV glycoprotein is produced by the method comprising the steps of:

growing a host cell transformed with a structural gene encoding an HCV glycoprotein expressed from the E1 region of HCV or the E2 region of HCV in a suitable culture medium;

causing expression of said structural gene, under conditions inhibiting sialylation; and

isolating said HCV glycoprotein from said cell culture by contacting said HCV glycoprotein with a mannose-binding protein specific for mannose-terminated glycoproteins, and isolating the protein that binds to said mannose-binding protein.

57. The antibody of claim 56, wherein said HCV glycoprotein is a glycoprotein expressed from the E1 region of HCV.

58. The antibody of claim 56, wherein said HCV glycoprotein is a glycoprotein expressed from the E2 region of HCV.

59. The antibody of claim 56, wherein said HCV glycoprotein is an aggregate of a glycoprotein expressed from the E1 region of HCV and a glycoprotein expressed from the E2 region of HCV.

60. The antibody of claim 56, wherein said HCV glycoprotein is an aggregate of glycoproteins expressed from the E1 region of HCV.

61. The antibody of claim 56, wherein said HCV glycoprotein is an aggregate of glycoproteins expressed from the E2 region of HCV.

62. The antibody of claim 56, wherein the antibody is a polyclonal antibody.

63. The antibody of claim 57, wherein the antibody is a polyclonal antibody.

64. The antibody of claim 58, wherein the antibody is a polyclonal antibody.

65. The antibody of claim 59, wherein the antibody is a polyclonal

antibody.

66. The antibody of claim 60, wherein the antibody is a polyclonal antibody.

67. The antibody of claim 61, wherein the antibody is a polyclonal antibody.

68. The antibody of claim 56, wherein the structural gene is linked to a sequence encoding a secretion leader that directs the glycoprotein to the endoplasmic reticulum and said conditions inhibiting sialylation comprise inhibiting transport of glycoproteins from the endoplasmic reticulum to the golgi.

69. The assay kit of claim 20, wherein said HCV glycoprotein is a glycoprotein expressed from the E1 region of HCV.

70. The assay kit of claim 20, wherein said HCV glycoprotein is a glycoprotein expressed from the E2 region of HCV.

71. The assay kit of claim 20, wherein said HCV glycoprotein is an aggregate of a glycoprotein expressed from the E1 region of HCV and a glycoprotein expressed from the E2 region of HCV.

72. The assay kit of claim 20, wherein said HCV glycoprotein is an aggregate of glycoproteins expressed from the E1 region of HCV.

73. The assay kit of claim 20, wherein said HCV glycoprotein is an aggregate of glycoproteins expressed from the E2 region of HCV.

74. The assay kit of claim 20, wherein the antibody is a polyclonal antibody.

75. The assay kit of claim 69, wherein the antibody is a polyclonal antibody.

76. The assay kit of claim 70, wherein the antibody is a polyclonal antibody.

77. The assay kit of claim 71, wherein the antibody is a polyclonal antibody.

78. The assay kit of claim 72, wherein the antibody is a polyclonal antibody.

79. The assay kit of claim 73, wherein the antibody is a polyclonal antibody.